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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,707	07/10/2002	Borje Rantala	2534-00068	7588
26753	7590	06/15/2006	EXAMINER	
ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 EAST WISCONSIN AVENUE, SUITE 1100 MILWAUKEE, WI 53202			SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	10/070,707		RANTALA ET AL.	
	Examiner		Art Unit	
	Kennedy Schaetzle		3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
- 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
- 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of grammatical errors too numerous to mention. Examples of such errors are as follows: "...problem is becoming the making..." (page 3, line 10); "...electrodes attached to the patent..." (page 5, lines 25 and 26); "...which in which..." (page 6, line 13); "...an analogy digital converter..." (page 8, lines 13 and 14), etc..

Appropriate correction is required.

Claim Objections

2. Claims 20 and 22-26 are objected to because of the following informalities: in claim 20, the reference to "...the ten electrodes..." on line 1 lacks antecedent basis; in claims 22-26 it is unclear if the applicant is referring to the remaining, additional electrodes set forth in base claim 19, or whether the applicant is attempting to recite structure in addition to what has previously been set forth (the examiner will assume the former and suggests the applicant insert the definite article "the" prior to the word "remaining"). Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 19-22 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al. (Pat. No. 4,577,639) in view of Donehoo et al. (Pat. No. 5,788,644).

Claim 19 is broad enough to read on any ECG system that allows selection of lead configurations. The first two attaching steps merely mimic what one must inherently do in order to attach electrodes for a standard 12-lead ECG test. Applicant's Fig. 3, for example, shows standard 10 electrode positioning for such an ECG measurement. Simon et al. disclose that typical lead configurations involve three, five,

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or twelve leads (see col. 1, lines 11-17) and that the invention may incorporate any of these known configurations (col. 2, lines 24-34). A standard 12-lead configuration employs 10 electrodes in the positions shown by applicants' Fig. 3 (see Fig. 2 of Donehoo et al.). Simon et al. teach to detect lead failures in an ECG system and switch to an alternate configuration when lead failure is detected in order to provide an acceptable ECG signal (see col. 1, lines 36-47). While Simon et al. discuss the particular condition of switching from a 5-lead to a 3-lead ECG to avoid bad leads, those of ordinary skill in the art recognizing the fact that the Simon et al. method may include a 12-lead system, would have seen the obviousness of switching from a 12-lead configuration to a 5-lead or 3-lead configuration (i.e., up to a 5-lead ECG) in order to reduce the effect of possible lead failures with the 12-lead configuration. Such a system allows one to obtain 12-lead ECG signal data and up to 5-lead ECG signal data when the 12-lead configuration is not available.

Regarding claim 20, the examiner considers the selection of electrode configuration based on the data to be obtained to be a matter of common sense. Nonetheless, Donehoo et al. teach that the number of leads used depends upon the desired characteristics to be monitored (see col. 3, lines 40-43). Regarding the use of 10 electrodes, again the applicants are referred to Fig. 2 of Donehoo et al. which shows what those of ordinary skill in the art would readily recognize to be a standard lead configuration for ECG measurements.

Regarding claims 21 and 22, the examiner considers the ECG signal processor of Simon et al. to inherently require operation of a selector switch to a first position in order to automatically switch out bad leads from the measurement process.

Regarding claim 28, see lead failure detector circuit 104 and col. 4, lines 37-52.

5. Claims 19-27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swenson et al. (Pat. No. 5,623,925) in view of Donehoo et al. (Pat. No. 5,788,644).

Regarding claim 19, Swenson et al. disclose a method for medical monitoring comprising attaching electrodes to a patient (conduit sets 52a-52h) in a manner to obtain EKG, EEG and EMG data. While a 12-lead EKG configuration is disclosed (see

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Table I), Donehoo et al. teach that the number of leads required for an EKG monitor depend upon the characteristics one desires to monitor (col. 3, lines 40-43). Although 5-lead ECG and IKG tests are not explicitly discussed, it would have been readily apparent from the disclosure of Swenson et al. that any number of diagnostic tests from the plethora of known tests available could have been employed in the practice of the Swenson et al. method. Clearly lead configurations of five leads or less are well-known to those of ordinary skill in the art. Such configurations are desirable when very detailed information such as provided by a 12-lead measurement is not necessary, or when less than all electrodes are optimally attached to the body. The type and number of tests performed is clearly not critical to the Swenson et al. invention as the main goal is to provide a testing machine that eliminates the need for separate, dedicated testing apparatus. Clearly the types of diagnostic tests associated with the method would depend upon the condition of the individual under treatment, with the decision residing with the physician responsible for the care and treatment of the patient. To include a 5-lead ECG (or 3-lead as in claim 29) and/or an IKG test as needed would have therefore been considered blatantly obvious by those of ordinary skill in the art.

Regarding claim 20, the examiner took Official Notice in the prior Office Action that the use of 10 conductors is standard in any 12-lead ECG test. The Official Notice has not been traversed and therefore such a feature is considered admitted prior art. Swenson et al. teach that multiple tests may be conducted with a common set of conductors (note for example col. 7, lines 28-36), with the conductor configuration being selected based on the measurement (note col. 2, lines 54-57).

Regarding claims 21 and 22, although Swenson et al. do not discuss a selector switch turned to any particular position, they do teach the need for a selector switch as per col. 2, lines 50-57, with the suggestion that the selector can be a computer keyboard, mouse or touch screen (col. 4, lines 48-58). The particular form that the switch takes is clearly immaterial to the invention as long as the option of selecting is made available to the operator.

Regarding claim 26, Official Notice is taken that it is old and well-known to determine the depth of anesthesia from EEG signal data.

Regarding claim 27, Swenson et al. teach that more than one test may use a common set of conduits (col. 7, lines 28-36). To use a common neutral electrode as a reference for both EKG and ECG would have therefore been considered a matter of obvious design, dependent upon the particular tests being performed. By using common conduits, Swenson et al. eliminate the need for additional, potentially cumbersome and inconvenient lead structure.

Regarding claim 29, note the comments made above regarding the obviousness of employing any number of leads to ascertain an ECG, with the exact number dependent upon the particular data of interest and the condition of the patient. Again, if a 2-lead EEG were considered sufficient to effectively diagnose a particular patient, then those of ordinary skill in the art looking to limit the complexity of the system and concomitant diagnosis would have seen the obviousness of employing only the number of leads needed to accurately obtain the desired information.

Regarding apparatus claims 30 and 31, note the comments made above for similar limitations. The use of preamplifiers is inherently necessary in order to detect the low-level biologically produced signals discussed above. See element 26 of Swenson et al. which acts through the universal interface.

6. Claims 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swenson et al. and Donehoo et al. as applied to claims 19-27 and 29-31 above, and further in view of Simon et al..

Swenson et al. do not discuss ascertaining the manner in which the electrodes are connected as determined by impedance relations. Simon et al., however, teach that it is highly beneficial to ascertain such data in order to identify faulty leads and enhance the monitoring accuracy of medical equipment (see col. 1, lines 36-47). To therefore enable similar detection of faulty connections associated with the conduits of Swenson et al. would have been considered blatantly obvious in order to improve signal detection capabilities. In any event, the examiner took Official Notice in the prior Office Action that it was old and well-known in the electrode art to monitor the state of electrode configurations by detecting an impedance signal associated therewith. Lacking an effective traversal, such a feature is now considered admitted prior art.

Response to Arguments

7. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

It is noted that the applicants contend that their invention is to be distinguished from the Swenson et al. invention in that it is possible to obtain EKG, EEG and IKG signal data simultaneously from a patient (see Remarks page 6, last paragraph). The examiner can find no disclosure of such operation. The selector switch set forth by the applicants does not allow for simultaneous measurement of different signals.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJS
June 12, 2006


KENNEDY SCHAETZLE
PRIMARY EXAMINER
6-12-06